DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 28, 2015

Vista Lifesciences, Inc.
c/o Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154
Trade/Device Name: ANAM Test System: Military Battery
Regulation Number: 21 CFR 882.1470
Regulation Name: Computerized Cognitive Assessment Aid
Regulatory Class: Class II
Product Code: PKQ
Dated: July 30, 2015
Received: July 31, 2015

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150154

Device Name
ANAM Test System: Military Battery

Indications for Use *(Describe)*

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name:	Computerized Cognitive Assessment Aid
Device Proprietary Name:	ANAM Test System: Military Battery
Applicant:	Vista LifeSciences, Inc. PO Box 4670 Parker CO 80134 Phone: 888.733.8804 Ext. 1 www.vistalifesciences.com
Contact:	Lori White Quality Systems Program Manager Vista LifeSciences, Inc. PO Box 4670 Parker CO 80134 Phone: 888.733.8804 Ext. 1 Email: lori.white@vistalifesciences.com
Prepared by:	Calley Herzog Senior Consultant Biologics Consulting Group, Inc. 400 N. Washington St. Suite 100 Alexandria, VA 22314 Email: cherzog@bcg-usa.com Phone: 720-883-3633 Fax: 703-548-7457
Date Prepared:	July 30, 2015
Classification Regulation:	882.1470
Panel:	Neurology
Product Code:	PKQ
Predicate Device:	DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's level of cognitive function.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both devices are computerized assessment aids that use an individual’s score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. In addition to perceptual and memory function, ANAM may be used as an adjunctive tool for evaluating additional functions including: visuomotor reaction time and processing speed, simple decision making, visual scanning, associative learning, visual-spatial processing, and attention.

	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
Indication	The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.	Cognivue is an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old.
Platform	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 operating system.	Computer, monitor, rotatory manipulandum, printer, and mouse/keyboard are provided on a device cart.
Use Cases	Reports individual test results and compares changes in individual tests over time and/or against military normative data.	Reports individual test results and compares overall performance to a cut-off.

	Proposed Device	Predicate Device
Patient Population	Military population	Adults
Age of Users	18-65 years	55-95 years
How Provided	Software only, downloaded	Software is pre-installed on computer hardware provided by the manufacturer.
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the military normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery.	Cognivue Performance Profile report yields a single output measure that is an average score of the four perception scores and four memory scores.
Psychometric Properties	ANAM demonstrates construct validity with traditional neuropsychological tests.	Cognivue demonstrates construct validity with traditional neuropsychological tests.
Results Interpretation	ANAM does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database. ANAM provides raw scores, standard scores, and reliable change indices for each test.	Cognivue provides an average score that is categorized as unimpaired, impaired, or intermediate/indeterminate based on comparison with a normative database. Sub-tests may not be evaluated individually.

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.